

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

FOREST LABORATORIES, INC., FOREST	)	
LABORATORIES HOLDINGS, LTD., and	)	
MERZ PHARMA GMBH & CO. KGAA,	)	
MERZ PHARMACEUTICALS GMBH,	)	
	)	
Plaintiffs,	)	C.A. No. 08-22-GMS
	)	
v.	)	
	)	
PLIVA D.D., PLIVA-HRVATSKA D.O.O.,	)	
BARR LABORATORIES, INC. and	)	
BARR PHARMACEUTICALS, INC.,	)	
	)	
Defendants.	)	

**ANSWER AND COUNTERCLAIMS BY DEFENDANTS PLIVA-HRVATSKA D.O.O.,  
BARR LABORATORIES, INC. AND BARR PHARMACEUTICALS, INC.**

Defendants PLIVA-Hrvatska d.o.o., Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. (collectively, "Defendants"), Answer the Amended Complaint of Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd. (together with Forest Laboratories, Inc. "Forest"), Merz Pharma GmbH & Co. KGaA and Merz Pharmaceuticals GmbH (together with Merz Pharma GmbH & Co. KgaA, "Merz") (collectively "Plaintiffs"), as follows:

1. Upon information and belief, based on the allegations of the Amended Complaint, Defendants admit that Forest Laboratories, Inc. is a Delaware corporation having a principal place of business at 909 Third Avenue, New York, New York 10022. Defendants otherwise deny the allegations of paragraph 1 of the Amended Complaint.

2. Upon information and belief, based on the allegations of the Amended Complaint, Defendants admit Forest Laboratories Holdings, Ltd. is an Irish corporation having offices at

Milner House, 18 Parliament Street, Hamilton JM11, Bermuda. Defendants otherwise deny the allegations of paragraph 2 of the Amended Complaint.

3. Upon information and belief, based on the allegations of the Amended Complaint, Defendants admit Merz Pharma GmbH & Co. KgaA is a German corporation having a principal place of business at Eckenheimer Landstraße 100, D-60318 Frankfurt am Main, Germany. Defendants otherwise deny the allegations of paragraph 3 of the Amended Complaint.

4. Upon information and belief, based on the allegations of the Amended Complaint, Defendants admit Merz Pharmaceuticals GmbH is a German corporation having a principal place of business at Eckenheimer Landstraße 100, D-60318 Frankfurt am Main, Germany. Defendants otherwise deny the allegations of paragraph 4 of the Amended Complaint.

5. Defendants admit that PLIVA d.d. is a Croatian corporation having a principal place of business at Ulica grada Vukovara 49, 10000 Zagreb, Croatia. However, Defendants deny that PLIVA d.d. has been properly served with the Summons and Amended Complaint.

6. Defendants admit that PLIVA-Hrvatska d.o.o. is a Croatian corporation having a principal place of business at Ulica grada Vukovara 49, 10000 Zagreb, Croatia.

7. Defendants admit that Barr Laboratories is a Delaware corporation with a place of business at 233 Quaker Road, Pomona, New York 10970. Defendants otherwise deny the allegations of paragraph 7 of the Amended Complaint.

8. Defendants deny the allegations of paragraph 8 of the Amended Complaint.

9. Defendants admit that, at present, Barr Pharmaceuticals, Inc. and PLIVA d.d. have at least one officer and one director in common, but deny that they have all officers and directors in common. Defendants otherwise deny the allegations of paragraph 9 of the Amended Complaint.

10. Defendants admit that PLIVA-Hrvatska d.o.o. is a wholly-owned subsidiary of PLIVA d.d. Defendants otherwise deny the allegations of paragraph 10 of the Amended Complaint.

11. Defendants admit that Barr Laboratories, Inc. is a wholly-owned subsidiary of Barr Pharmaceuticals, Inc. Defendants admit that, at present, Barr Pharmaceuticals, Inc. and Barr Laboratories, Inc. have at least one officer and one director in common, but deny that they have all officers and directors in common. Defendants otherwise deny the allegations of paragraph 11 of the Amended Complaint.

12. Defendants deny the allegations of paragraph 12 of the Amended Complaint.

13. Defendants deny the allegations of paragraph 13 of the Amended Complaint.

14. The allegations of paragraph 14 of the Amended Complaint state a legal conclusion to which no response is required. Defendants admit that Plaintiffs purport to state a claim for infringement of United States Patent No. 5,061,703 ("the '703 patent") under the patent laws of the United States, arising under 35 U.S.C. § 271(e)(2)(A), 271(a), (b) and/or (c). Defendants deny the remaining allegations of paragraph 14 of the Amended Complaint.

15. The allegations of paragraph 15 of the Amended Complaint state a legal conclusion to which no response is required. Defendants admit that Plaintiffs purport to base

subject matter jurisdiction on 28 U.S.C. §§ 1331 and 1338(a). Defendants deny the remaining allegations of paragraph 15 of the Amended Complaint.

16. Defendants deny that PLIVA d.d. and PLIVA-Hrvatska d.o.o. have any presence in Delaware, or any systematic and continuous contacts with Delaware, and further deny that this Court has personal jurisdiction over PLIVA d.d. and PLIVA-Hrvatska d.o.o. for the reasons alleged in paragraph 16 of the Amended Complaint. However, for the purposes of this action, PLIVA-Hrvatska d.o.o. submits to personal jurisdiction in this Court. Defendants deny the remaining allegations of paragraph 16 of the Amended Complaint. In addition, Defendants deny that PLIVA d.d. has been properly served.

17. Defendants admit that this Court has personal jurisdiction over Barr Pharmaceuticals, Inc. and Barr Laboratories, Inc.

18. Defendants admit that the face of the '703 patent, titled "Adamantane Derivatives in the Prevention and Treatment of Cerebral Ischemia," states that it was issued by the United States Patent and Trademark Office ("USPTO") on October 29, 1991. Defendants lack knowledge or information sufficient to form a belief as to the remaining allegations of paragraph 18 of the Amended Complaint, and therefore deny them.

19. Defendants admit that the '703 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for Namenda. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 19 of the Amended Complaint, and therefore deny them.

20. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 20 of the Amended Complaint, and therefore deny them.

21. Defendants admit that USPTO records indicate that on August 18, 2004, Merz submitted a request to the USPTO for reexamination of the '703 patent. Defendants admit that USPTO records indicate that the USPTO issued a reexamination certificate for the '703 patent on November 7, 2006. Defendants lack knowledge sufficient to form a belief as to the truth of the remaining allegations of paragraph 21 of the Amended Complaint, and therefore deny them.

22. Defendants admit that Barr Laboratories, Inc., acting as U.S. agent for PLIVA-Hrvatska d.o.o., submitted Abbreviated New Drug Application ("ANDA") No. 90-045 with the FDA under 21 U.S.C. § 355(j) seeking approval for the commercial manufacture, use and sale of generic tablet products containing 5 milligrams and 10 milligrams of memantine hydrochloride. Defendants deny that Barr Pharmaceuticals, Inc. participated in the submission of ANDA No. 90-045. Defendants further deny the remaining allegations of paragraph 22 of the Amended Complaint.

23. Defendants admit that ANDA No. 90-045 contains a statement that in the applicants' opinion, and to the best of their knowledge, the '703 patent is invalid, unenforceable and/or not infringed by the commercial manufacture, use or sale of the applicants' memantine hydrochloride. Defendants admit that, by a letter dated December 7, 2007, the ANDA applicants notified Forest and Merz that the FDA received an ANDA from the applicants with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Defendants admit that, upon information and belief, this letter was delivered to Forest and Merz on or about December 10,

2007. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 23 of the Amended Complaint, and therefore deny them.

24. Defendants admit that a supplemental Notice Letter, dated January 15, 2008, was sent by the ANDA applicants to Forest and Merz with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Defendants admit that, upon information and belief, this letter was delivered to Forest and Merz on or about January 16, 2008. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 24 of the Amended Complaint, and therefore deny them.

25. Defendants admit that the submission of ANDA No. 90-045, including the certification under § 505(j)(2)(A)(vii)(IV) that the '703 patent is not infringed, is invalid and is unenforceable, is sufficient to confer subject matter jurisdiction pursuant to § 271(e)(2) against the ANDA applicants. Defendants deny the remaining allegations of paragraph 25.

26. Defendants admit that they were aware of the '703 patent prior to the filing of ANDA No. 90-045. Defendants deny the remaining allegations of paragraph 26 of the Amended Complaint.

27. Defendants deny the allegations of paragraph 27 of the Amended Complaint.

## **DEFENSES**

### **FIRST DEFENSE (Noninfringement)**

28. The manufacture, use, or sale, of memantine hydrochloride pursuant to ANDA No. 90-045 will not infringe any valid, enforceable claim of the '703 patent.

**SECOND DEFENSE**  
**(Invalidity)**

29. The claims of the '703 patent are invalid for failure to comply with one or more of the conditions for patentability as specified in Title 35 U.S.C. §§ 1 *et seq.*

**THIRD DEFENSE**  
**(Improper Broadening Reexamination)**

30. If any of the claims of the '703 patent are construed to cover the manufacture, use or sale of memantine hydrochloride pursuant to ANDA No. 90-045, those claims of the '703 patent are invalid for failure to comply with the conditions for patentability as specified in Title 35 U.S.C. § 305.

**FOURTH DEFENSE**  
**(Failure to State a Claim Upon Which Relief Can be Granted)**

31. The Amended Complaint fails to state a claim against the Defendants upon which relief may be granted.

**COUNTERCLAIM FOR DECLARATORY JUDGMENT**

**Jurisdiction and Venue**

32. This counterclaim by ANDA applicants PLIVA-Hrvatska d.o.o. and Barr Laboratories, Inc. (collectively "Counterclaimants") arises under the Declaratory Judgment Act and the Patent Laws of the United States, more particularly under 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. §§ 1 *et seq.*, respectively. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1338 and 2201. Venue is proper under 28 U.S.C. §§ 1391 and 1400(b), and by the Counterdefendant's choice of forum.

33. An actual and justiciable controversy exists between Counterclaimants and Counterdefendants as to the infringement and validity of the patents in suit, as evidenced, inter alia, by the Amended Complaint and Answer in this action.

### **The Parties**

34. PLIVA-Hrvatska d.o.o. is a Croatian corporation having a principal place of business at Ulica grada Vukovara 49, 10000 Zagreb, Croatia.

35. Barr Laboratories, Inc. is a Delaware corporation with a principal place of business at 225 Summit Avenue, Montvale, New Jersey, 07645.

36. Upon information and belief, based on the allegations of the Amended Complaint, Forest Laboratories, Inc. is a Delaware corporation having a principal place of business at 909 Third Avenue, New York, New York 10022.

37. Upon information and belief, based on the allegations of the Amended Complaint, Forest Laboratories Holdings, Ltd. is an Irish corporation having offices at Milner House, 18 Parliament Street, Hamilton JM11, Bermuda.

38. Upon information and belief, based on the allegations of the Amended Complaint, Merz Pharma GmbH & Co. KGaA is a German corporation having a principal place of business at Eckenheimer Landstraße 100, D-60318 Frankfurt am Main, Germany.

39. Upon information and belief, based on the allegations of the Amended Complaint, Merz Pharmaceuticals GmbH is a German corporation having a principal place of business at Eckenheimer Landstraße 100, D-60318 Frankfurt am Main, Germany.



### **The Controversy**

40. Upon information and belief, on October 29, 1991, the '703 patent was issued by the USPTO.

41. Upon information and belief, Merz has been an assignee of the '703 patent since its issuance.

42. Upon information and belief, Forest is a licensee of the '703 patent in the United States.

43. Upon information and belief, Merz submitted a request to the UPSTO on August 18, 2004 for the reexamination of the '703 patent.

44. Upon information and belief, the USPTO issued a reexamination certificate for the '703 patent on November 7, 2006.

45. Barr Laboratories, Inc., acting as U.S. agent for PLIVA-Hrvatska d.o.o., submitted ANDA No. 90-045 with the FDA under 21 U.S.C. § 355(j), seeking approval for the commercial manufacture, use and sale of generic tablet products containing 5 milligrams and 10 milligrams of memantine hydrochloride.

46. ANDA No. 90-045 contains a statement that in the applicants' opinion and to the best of their knowledge, the '703 patent is invalid, unenforceable and/or not infringed by the commercial manufacture, use or sale of applicants' memantine hydrochloride.

47. In a letter dated December 7, 2007, the ANDA applicants notified Forest and Merz that the FDA had received an ANDA with a certification pursuant to 21 U.S.C. §

355(j)(2)(A)(vii)(IV). This letter was delivered to Forest and Merz on or about December 10, 2007.

48. The ANDA applicants sent a supplemental Notice Letter, dated January 15, 2008, to Forest and Merz with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). This letter was delivered to Forest and Merz on or about January 16, 2008.

### **COUNT I**

#### **Declaratory Judgment of Non-Infringement of the '703 Patent**

104. The commercial manufacture, use, offer to sell, sale, or importation of memantine hydrochloride pursuant to ANDA No. 90-045 shall not constitute infringement of the '703 patent.

### **COUNT II**

#### **Declaratory Judgment Of Invalidity Of The '703 Patent**

105. The claims of the '703 patent are invalid for failure to comply with the conditions for patentability as specified in Title 35 U.S.C. §§ 1 *et seq.*

### **COUNT III**

#### **Declaratory Judgment Of Improper Broadening Reexamination Of The '703 Patent**

106. If any of the claims of the '703 patent are construed to cover the manufacture, use or sale of memantine hydrochloride pursuant to ANDA No. 90-045, those claims of the '703 patent are invalid for failure to comply with the conditions for patentability as specified in Title 35 U.S.C. § 305.

**PRAYER FOR RELIEF**

WHEREFORE, Counterclaimants pray that the Court enter judgment against Plaintiffs:

- A. Denying all relief sought in the Amended Complaint, and dismissing the complaint with prejudice;
- B. Declaring that the claims of the '703 patent are invalid;
- C. Declaring that the claims of the '703 patent are not, and will not be, infringed by the manufacture, use, offer for sale, sale, and/or importation of memantine hydrochloride pursuant to ANDA No. 90-045;
- D. Enjoining Counterdefendants, their assigns, and all those in privity therewith from asserting the '703 patent against Counterclaimants or any of their customers or suppliers;
- E. Awarding Counterclaimants their attorneys' fees pursuant to 35 U.S.C. § 285, and their costs and expenses; and
- F. Awarding Counterclaimants such other and further relief as may be just and proper.

POTTER ANDERSON & CORROON LLP

OF COUNSEL:

Thomas J. Meloro  
Eugene L. Chang  
Colman B. Ragan  
WILLKIE FARR & GALLAGHER LLP  
787 Seventh Avenue  
New York, N.Y. 10019-6099  
Tel: (212) 728-8000

Dated: March 3, 2008  
852443 / 32643

By: /s/ David E. Moore

Richard L. Horwitz (#2246)  
David E. Moore (#3983)  
Hercules Plaza, 6<sup>th</sup> Floor  
1313 N. Market Street  
Wilmington, Delaware 19801  
Tel: (302) 984-6000  
[rhorwitz@potteranderson.com](mailto:rhorwitz@potteranderson.com)  
[dmoore@pottersanderson.com](mailto:dmoore@pottersanderson.com)

*Attorneys for Defendants PLIVA d.d., PLIVA-Hrvatska d.o.o., Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc.*

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**CERTIFICATE OF SERVICE**

I, David E. Moore, hereby certify that on March 3, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I hereby certify that on March 3, 2008, I have Electronically Mailed the document to the following person(s)

Jack B. Blumenfeld  
Maryellen Noreika  
Morris, Nichols, Arsht & Tunnell LLP  
1201 North Market Street  
P.O. Box 1347  
Wilmington, DE 19899  
[jblumenfeld@mnat.com](mailto:jblumenfeld@mnat.com)  
[mnoreika@mnat.com](mailto:mnoreika@mnat.com)

F. Dominic Cerrito  
Daniel L. Malone  
Eric C. Stops  
Jones Day  
222 East 41<sup>st</sup> Street  
New York, NY 10017  
[fdcerrito@jonesday.com](mailto:fdcerrito@jonesday.com)  
[dlmalone@jonesday.com](mailto:dlmalone@jonesday.com)  
[estops@jonesday.com](mailto:estops@jonesday.com)

/s/ David E. Moore  
Richard L. Horwitz  
David E. Moore  
Potter Anderson & Corroon LLP  
Hercules Plaza – Sixth Floor  
1313 North Market Street  
Wilmington, DE 19801  
(302) 984-6000  
[rhorwitz@potteranderson.com](mailto:rhorwitz@potteranderson.com)  
[dmoore@potteranderson.com](mailto:dmoore@potteranderson.com)

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